



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-00-47

April 10, 2000

Gilbert R. Migliano, President
Save On Seafood Company, Inc.
4520 8th Avenue South
St. Petersburg, Florida 33711

Dear Mr. Migliano:

We inspected your seafood processing plant on March 28, 2000 and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation causes your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

The deviation is as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for various species of fresh and frozen raw fish in Modified Atmosphere Packaging to control the biological hazard of *Clostridium botulinum* toxin formation. This deviation was previously brought to your attention in our letter of June 8, 1999.

Packaging conditions that exclude oxygen favor the growth of *Clostridium botulinum*. This potential food safety hazard is reasonably likely to occur in your raw unpreserved fish products in Modified Atmosphere Packaging. You should determine preventive measures and evaluate those measures, either singularly, or in combination to demonstrate how you intend to control this potential hazard without additional preservation.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products in Modified Atmosphere Packaging to European Union (EU) countries if you do not correct this deviation.

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Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as copies of your hazard analysis, HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you believe the deviation will be corrected.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the GMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward R. Atkins". The signature is fluid and cursive, with the first name "Edward" being the most prominent part.

Edward R. Atkins
Acting Director
Florida District